Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

Non WHO Reference Material
Soluble Tumour Necrosis Factor Receptor TYPE II
NIBSC code: 93/524
Instructions for use
(Version 5.0, Dated 30/04/2013)

This material is not for in vitro diagnostic use.

1. INTENDED USE

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as1. potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in2. opening ampoules or vials, to avoid cuts.

3. UNITAGE

The exact amount of soluble TNF receptor required to neutralise TNF will be dependent on the TNF concentration used in the assay method employed. Bioassay calibration using an appropriate TNF ligand with a suitable dilution of the sTNF-RII should be determined for individual methods. The following informtion is provided as a guide, based on bioassays performed at NIBSC.

After reconstitution, a 1:1000 dilution of the ampoule contents neutralised the cytototoxic activity of 20 IU/ml of the International standard for TNF alpha using KD4-clone 21 cells.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1.0 ml of a solution containing:
Soluble TNF-RII, approximately 10 micrograms
Potassium Phosphate buffer
1.0 mg Trehalose
2.0 mg Human serum albumin

The soluble TNF-RII was expressed in CHO cells.

5. STORAGE

For economy of use, it is recommended that the solution be sub-divided into several small aliquots and stored at -40°C or below. Avoid repeated thawing/freezing. Unopened ampoules should be stored at -20°C.
Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material. Dissolve the total contents of the ampoule with 0.5ml of sterile distilled water. Rinse the ampoule with about 0.4ml of sterile distilled water and make up the total volume to 1.0ml. This solution will contain soluble TNF-RII at a concentration of 10 micrograms/ml. Use carrier protein where extensive dilution is required.

8. STABILITY

This preparation has not been assessed for long term stability, but evidence from similar materials prepared by an equivalent process indicates that long term stability is likely to be maintained and the material is suitably stable for shipment at ambient temperature. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use. Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

Meager, A., 1991. A cytotoxicity assay for tumour necrosis factor using a human rhabdomyosarcoma cell line. Journal of Immunological Methods **144**, 141.

Meager, A., 1999. A tumour necrosis factor-alpha Journal of Immunological Methods (TNF alpha) sensitive adherent KYM-1D4 derived cell line: use in TNF alpha□ytotoxicity assays in the presence of actinomycin D **227**, 197

10. ACKNOWLEDGEMENTS

N/A

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

Physical and Chemical properties	
Physical appearance: Freeze-dried	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic:No	Irritant: No

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

Flammable: No	Handling: See caution, Section 2
Other (specify): contains material of human origin	
Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion: Not established, avoid ingestion	
Effects of skin absorption:	Not established, avoid contact with skin
Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion: Seek medical advice	
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.
Action on Spillage and Method of Disposal	
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.	

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 4.6g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No